K950264

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1. **Date this summary was prepared :** December 18, 1995

2. **Submitter's Name and Address :**

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3. **Device Name**

Trade / Proprietary Name	:	MAGLIFE®
Common Name	:	MRI-Compatible Vital Signs Monitor
Classification Name	:	Patient Monitor

4. **Predicate Device**

The legally marketed device to which equivalence is being claimed :

* OMNI TRAK 3100 MRI
In vivo Research Inc
12601 Research Parkway
ORLANDO FL 32826
USA

510(k) numbers : K864889 - K935020

5. **Device Description**

The MAGLIFE® MRI-Compatible Vital Signs Monitor is a complete patient monitoring system designed to be installed inside the Faraday Cage. It monitors ECG, arterial blood oxygen saturation, pulse rate, expired end tidal CO_2 ($etCO_2$), N_2O concentration ($\%N_2O$), minimum inspired CO_2, respiration rate, noninvasive blood pressure, and invasive blood pressure.

The system consists of three enclosures ; a power supply which is permanently anchored to the floor, an operator console which includes a display and control keypad, and a connection box which is placed near the magnet opening and accepts the patient connections.

Output of information includes real-time display of waveforms, digital display of calculated parameters, and audible and visual alarm indicators.

Accessories include nonmagnetic patient connections for all parameters.

Safety of the operator and patient is ensured by compliance to IEC 601-1.

6. Intended Use

The MAGLIFE® is a device for monitoring the vital signs of patients who are undergoing a Magnetic Resonance Imaging examination. This device is designed for this special environment where ordinary patient monitoring equipment cannot be used for the following reasons :

* The magnetic and electric fields present in the vicinity of the MRI can interfere with the proper operation of ordinary monitors.

* The presence of ferromagnetic materials in an ordinary monitor may influence the homogeneity of the magnetic field and thereby degrade the quality of the image acquired.

* Some magnetic materials can become dangerous projectiles in the presence of large magnetic fields.

The indications for use are identical to the indications for vital signs monitoring of patients not undergoing MRI examinations.

7. Comparison of Technological Characteristics

Both the OMNI TRAK 3100 MRI and the MAGLIFE® are multi-parameter vital signs monitors that can be installed inside the Faraday cag for monitoring patient undergoing MRI examinations. Both designs use well accepted measurement techniques that have been modified to optimize performance in the presence of the magnetic and electric fields found in the vicinity of the MRI and to prevent interference with the quality of the images. Both monitor ECG, arterial blood oxygen saturation, pulse rate, expired end tidal CO_2 ($etCO_2$), N_20 concentration ($\%N_2O$), minimum inspired CO_2, respiration rate, non-invasive blood pressure.

The two systems differ in the following respects :

- Only the MAGLIFE® offers Invasive Blood pressure.

- Only the MAGLIFE® offers a pulse oximetry sensor for use on the ear.

- MAGLIFE® is intended to be permanently installed in a fixed location within the Faraday cage, while the OMNI TRAK 3100 MRI is a portable unit, installed outside of the shielding room.

8. Nonclinical Tests Used in Determination of Substantial Equivalence

MAGLIFE is certified (by GLEM Laboraty) about :

- Security of medical devices : NFC 74-010 (CEI 601-1) - NFC 74-380

- Performance of each module : NFC 74-381 - NFC 74-382 - NFC 74-388

MAGLIFE obtained French approval by the French health ministery.
MAGLIFE obtained GS Label from DEKRA in Germany (Stuttgart)

9. Clinical Tests Used in Determination of Substantial Equivalence

More than 200 patients (80 % babies, 5 % adults under anaesthesia) were monitored over a two year period. About 25 % of the babies were premature with a weight less than 2 kg. The parameters used most were the SaO_2 and the ECG. The optical SaO_2 sensor is more sensitive to motion artifact than the electrical one especially in the case of babies.

For the ECG, in the majority of cases there are less than 10 % signal artifacts during the scan. Because of the lead used, the increased motion artifacts, and the extra deviation of the ST segment due to the BO, the ECG is useful mainly for monitoring rhythm. The quality of the signal depends on the electrode positioning, the coil, the MR-sequence, and the patient. In a few cases the ECG was not usable.

10. Conclusions from Nonclinical and Clinical Testing

The non-clinical testing showed that all parameters can be monitored in the MRI environment with no significant loss of accuracy.

The clinical studies showed that, with experience and operator training, the MAGLIFE® can monitor all desired parameters in most patients and does not produce any detectable image distortions or artifacts.

The combination ECG-SaO_2-Capnography was useful essentially for premature babies. Invasive and noninvasive blood pressure are important in adults.

11. Other Information Deemed Necessary by FDA

The 510(k) Summary is used by FDA when a member of the public requests information about your 510(k). FDA will send out a copy of only the summary to anyone who requests information. it should be brief, but should mention all the points listed above.

* The summary includes only information that is also covered in the body of the 510(k).
* The summary does not contain any puffery or unsubstantiated claims.
* The summary does not contain any raw data, i.e., contains only summary data.
* The summary does not contain any trade secret or confidential commercial information.
* The summary does not contain any patient identification information.